

BASES OF SUIT

1. Jurisdiction and nature of suit

Article 22.1 of the Judiciary Act, as regards the competence of the Spanish courts to instruct this suit, regarding article 36 of the Civil Prosecution Act 1/2000 of 7th January (hereinafter, Act 1/2000).

Article 125.1 of the Patents Act, in the text given to same by the Final Fifth provision of Act 1/2000, according to which:

"Civil suits arising within the scope of this Act shall be settled in the trial that corresponds according to the Civil Prosecution Act".

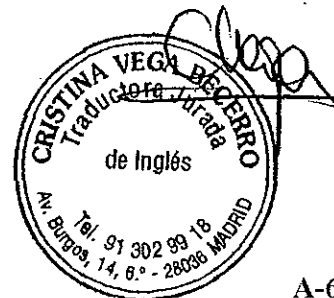
Article 249.1.4^o of the Civil Prosecution Act 1/2000, regarding the kind of suit applicable and within the scope of the Ordinary Suit, to whose substantiation the following are assigned:

" 4.º Suits on the matter of unfair competition, industrial property, intellectual property and advertising, as long as they are not exclusively over quantity claims, in which case they shall be subject to the procedure corresponding depending on the amount being claimed".

2.Objective Competence

Item 2 of article 86 ter of the Civil Prosecution Act (according to the modification introduced by Organic Law 8/2003 of 9th July on Competition reform), regarding the competence of the Mercantile Courts on the matter of industrial property, by which:

"2. The mercantile courts shall also examine any issues regarding the following, when they fall under the competence of the civil jurisdictional order:



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- a) *Suits in which action is taken regarding unfair competition, industrial property, intellectual property and advertising, as well as all issues that are promoted within this jurisdictional order under the auspices of the regulations governing mercantile companies and co-operatives".*

3. Territorial competence

Number 13 in item 1 of article 52 of the Civil Prosecution Act, by which:

"On the matter of patents and trademarks, the Court indicated by the special legislation on this matter shall be competent".

Item 2 of article 125 of the Patents act, by which:

" The Judge of 1st Instance of the city where the Higher Court of Justice of the Autonomous Community corresponding to the defendant's domicile shall be competent".

4. Legitimation

The plaintiff company, ETHYPHARM, S.A. is actively legitimated to exercise this suit, as the holder of the Patent that is the object of the said suit, in conformity with the terms of article 62 of the Patents Act of 20th March 1986, as regards article 10 of Act 1/2000.

The defendant is passively legitimated to bear this suit as the company in charge of manufacturing and selling the products that infringe upon the exclusive rights derived from the aforementioned industrial property registration.

5. Postulation

Representation by a Solicitor and assistance by an Attorney are mandatory, as it is an Ordinary Suit that is not exempt from Postulation, according to the terms of articles 23 and 31 of Act 1/2000.

6. Probatory Activity

Article 328 of act 1/2000, regarding the obligation of the parties to show documentation, by which:

" 1.Each of the parties may request that the other parties show documents not in the former's possession and referring to the object of the suit or to the efficiency of the means of evidence.

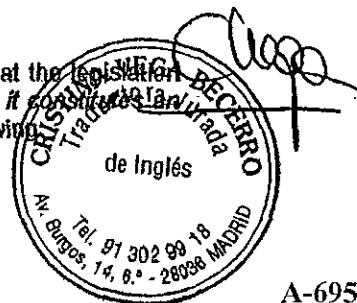
2. Requests to show documents must be accompanied by a simple copy of the document and, if it does not exist or is not available, the content of same shall be indicated in the most exact terms possible."

-II-

RIGHTS DERIVED FROM THE PLAINTIFF'S OWNERSHIP OF THE PATENT ES 9301319 AND INFRINGEMENT OF SAME IN THE MANUFACTURE AND SALE OF OMEPRAZOL BY THE DEFENDANT

1. Notion and regulation for patent

The Spanish Patents Act of 20th March 1986 acknowledges in its Preamble that the legislation on this matter "has a decisive influence on how the economy is organised, as it constitutes an essential element for promoting technological innovation", also adding the following:



manufacture procedure is used. If the result of the procedure still results in the same formulation, the infringement subsists.

3. Infringement of a patent by equivalence

When considering if the infringing product constitutes an infringement of the patent, any changes that have been introduced but which have not led to any change in the result are entirely lacking in importance. Our legal system also contemplates the infringement of a patent by equivalence.

In fact, the doctrine of equivalence is understood to mean that which postulates a wide interpretation of the content of the patented invention in order to avoid unconsented use by third parties of technical solutions which, although not included in literal terms in the claims for the patent, present insubstantial variations on the elements contained in same. The doctrine departs from the need to protect the patent beyond what its claims express *ad pedem litterae*. By virtue of this doctrine, the patent is understood to protect not only the elements that are explicitly mentioned in the claims, but also all other elements or forms of embodiment that despite being alternatives, lead to equivalent results.

This doctrine of equivalence is currently supported by an unquestionable legal structure. Among other regulatory provisions, we beg to quote the following:

- Article 50.1 of the Patents Act, according to which,

"The extension of the protection conferred by the patent or by the patent application is determined by the content of the claims. However, the description and the drawings serve to interpret the claims".

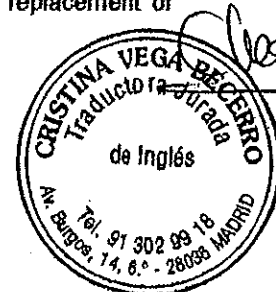
- Article 69.1 of the Agreement of 5th October 1973 on the granting of European patents, which entered into force in Spain as from 1st October 1986, by which:

"The scope of the protection afforded by the European patent or European patent application shall be determined by the content of the claims. However, the description and the drawings shall serve to interpret the claims".

- The protocol that interprets the Agreement on European patents, which forms an integral part of same, containing the following statement:

"Article 69 should not be interpreted in the sense that the scope of the protection afforded by the European patent should be understood according to the strict and literal meaning of the text of the claims and that the description and the drawings serve solely to dissipate ambiguities that may be contained in the claims. Neither should it be interpreted in the sense that the claims serve only as a guideline and that the protection is extended also to what, in the opinion of an official person that has examined the description and the drawings, the holder of the patent wished to protect. Article 69 should rather be interpreted in the sense that defines, among other things, a position that ensures at the same time fair protection for the applicant and a reasonable degree of certainty to third parties."

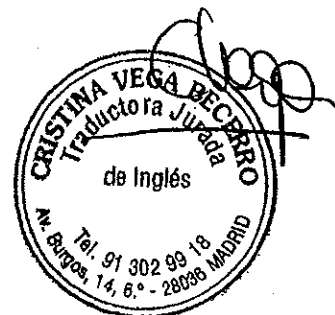
The doctrine of equivalence is currently a consolidated doctrine in Spanish case law. The courts have laid down that when the changes do not affect the global notion of the invention or the essential principle that inspires the latter, representing merely the replacement of some elements by others, the infringement still stands.



The 1st Courtroom of the Supreme Court seemed to come close to the doctrine of the "general inventive concept" in its sentence of 13th December 1989, declaring that:

"Nobody can take advantage of another's idea in order to present it as its own under the pretext of having introduced small and insubstantial modifications in the layout or use".

The 15th Section of the Provincial Court of Barcelona first referred to the doctrine of equivalence in its sentence of 15th March 2000 (JUR 2000/ 182856), indicating in this regard:



" FIFTH. The plaintiff, both in the explanations requested from the experts and in the last statements made in the second instance, centres the question on what is considered to be the equivalence between the component for guiding the coils, as is claimed in intervention patent number 541.248 held by SUPERBA and the component for guiding the coils foreseen in the HB1 machine by MOTOCONO, in its three versions.

It refers basically to what constitutes an infringement by equivalence and quotes, among others, the Sentence from the Contentious-Administrative Courtroom of the Supreme Court of 5th December 1967, in the sense that it is not possible to avoid the course of the principle of equivalence by which, in the protection of any registered invention, it is understood to include all the variations in terms of form, material, size, layout of elements or any replacement of these elements by others, if this does not alter the fundamental principle of the invention described, claimed and protected by the patent or the utility model already in existence in the registration.

The plaintiff states that the equivalence between the coil guiding components is not dismissed by the fact that in the case of SUPERBA, the guiding component is a single part (sable) and in the case of MOTOCONO, two parts (sable or collar + application guide) because both solutions fulfil the same function, operate in the same manner and obtain the same result."

QUERALT VILA VERGES, sworn translator English-Catalan nº 718, hereby certifies that this translation is faithful to the original document written in Catalan.

In witness whereof, I have hereunto set my hand this June 8th 2005, in Barcelona.

QUERALT VILA VERGÉS

Núm. 718 N.I.F. 38141879-J

Traductora-Intèrpret Jurada Anglès-Català

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However, it is in the sentence issued by the Provincial Court of Barcelona (15th Section) of 16th September 2000 (AC 2054) where the principle of equivalence was finally established. The terms in which the sentence is issued are as follows:

"As a rule, it may be said that, according to the terms of article 25 of the Patents Act, the claims define the object for which protection is sought, which means that, according to 60.1, "extension of the protection conferred by the patent or by the patent application is determined by the content of the claims".

However, efficient protection of the right of the inventors does not tolerate that the monopoly be overcome by introducing in the invention any irrelevant modification that destroys the absolute equality between the invention and the new procedure, giving rise to the doctrine of "equivalence", whereas the latter is understood to mean "variations in terms of form, material, size, layout of elements or any replacement of these elements by others, if this does not alter the fundamental principle of the invention described, claimed and protected by the patent or the utility model" (sentence from 3rd Courtroom of 10th June 1968 [RJ 1968/ 3155]), or "when the means perform the same function to achieve an identical result despite the fact that the forms of embodiment may be different"; fulfilling the same function "when they proceed from the same basic idea, i.e. when they apply the same principle in the same manner", whereas the result is identical when "it is of the same nature and the same quality" (decision of 15th June 1994 in appeal no. T 697/1992 of the European Patents Office).

In our sentences of 3rd January (AC 2000/685) and 10th February this year – Bayer vs. Impex (case of ciprofloxacin), and Pfizer vs. Cehmo Ibérica (case of fluconazol)-, in cases that present certain similarities, we adopted the position maintained by the Supremo Court in its sentences of 13th October 1975 (RJ 1975/3420) and 13th October 1982 (RJ 1982/5761), whereas the concept of chemical or pharmaceutical procedure is understood to be delimited by the combination of three elements: the basic departing substance; the procedure followed on this substance; and the end product or result."

This case law has been ratified in the recent sentence of the 15th Section of the Provincial Court of Barcelona on 14th October 2002 (JUR 2004/14120), according to which:

"In order to examine the infringement exercised by the reconvention method (and symmetrically, the jactitation suit intended by the defendant, which was assessed in the sentence of 1st Instance), it is not irrelevant to point out that the theory of the claims that determines efficient protection of the rights of the inventors (and which is applicable to the utility models by the reference made in article 154), does not lose its validity because of the simple introduction of any irrelevant modification that destroys the absolute identity between the controverted model with which it was registered by the plaintiff, which constitutes the theory of equivalence (to which the plaintiff referred in the minutes of the hearing and which was mentioned in our sentence of 14th January 1999 – Roll 131/97-), whereas these are understood to mean "variations in terms of form, material, size, layout of elements or any replacement of these elements by others, if this does not alter the fundamental principle of the invention

described, claimed and protected by the patent or the utility model", or when "the means perform the same function to achieve an identical result despite the fact that the forms of embodiment may be different"; fulfilling the same function "when they proceed from the same basic idea, i.e. when they apply the same principle in the same manner", whereas the result is identical when "it is of the same nature and the same quality" (decision of 15th June 1994 in appeal no. T 697/1992 of the Spanish Patents Office).



SEVENTH. Recognition of the apparatus provided for the initiatives marketed by SOLAC, S.A., by the names "Professional Epil", "Super Epil" and "Hidratant Epil" indicates the existence of a series of circumstances that are common to those described by model no. 8900037 contained in the aforementioned report issued by the SPTMO f. 1.169, i.e.: a) they are formed by a shell that is formed by two half-shells; b) there is a sleeve inside the shell; c) the shells are divided in two parts on the longitudinal plane; d) there are resistances attached to the side and outer surface of the sleeve; e) the wax containing deposits present a configuration to that of the shell that houses them; f) the resistances, in this particular device, are governed by a fixed thermostat in order to maintain an ideal temperature for applying the wax; g) the shell, the sleeve and the electrical resistances are fitted together so as to form a small body, which in combination with a complementary container deposit allows to perform a hair removal process in which the wax remains hot for the whole process of hair removal; h) the wax applying device is portable.

Without prejudice to the differences in what was called the philosophy of use of the utensils being compared (as was noted by the expert that intervened in proceeding 866/06 followed before Court no. 43 in Barcelona), the remaining differences between both (the fact that the plaintiff's device was formed by a single part and the defendant's by two, the fact of one having a handle and a switch and not the other and the fact that the device protected by utility model 8900037 had constant connection to the electrical network – which may be eliminated by means of the function the device is called to perform without detriment to same – and not the one marketed by the defendant), may be considered to be non transcendent, as the purpose and the mode of operation of the instruments examined are the same. Thus concludes the repeated report from the SPTMO – f. 1.472 – and this is the conclusion to which the Courtroom arrives, which means that the appealed sentence is repealed and the reconvention suit filed by the plaintiffs is accepted, with the consequences of cessation, seizure and destruction of all of the products that infringe upon the protected right and of the frames used by ELECTRODOMESTICOS SOLAC, S.A. to manufacture same".

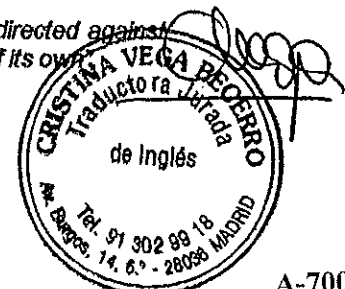
4. Lack of any virtue in possible allegation to the contrary based on LABORATORIO BELMAC, S.A.'s patent no. 2192929: articles 55 and 56 may be invoked for this purpose

The fact that LABORATORIOS BELMAC, S.A. is in possession of an invention patent for the manufacture of Omeprazole – regardless of whether it may be being used or not – does not exonerate the defendant of its liability for infringement of patent no. ES 9301319.

(a) Patent no. 2192929 was applied for by the defendant at a later date after ETHYPHARM's patent and regarding a technology that had been provided to the former by the plaintiff and which the former had been applying with the machinery owned by the plaintiff. In this regard, we should remember that the rights must be exercised on a bona fide basis and that the system does not support either the abuse of law or actions performed outside the law. Articles 6.4 and 7 of the Civil Code constitute an elementary departure point in this regard.

(b) The Patents Act expressly regulates this type of cases in which the defendant intends to support its action on a registration that is more recent than the one on which the suit for violation filed against the defendant is based. We refer here to article 55 of the Act, according to which:

"The holder of a patent may not invoke the latter to defend itself against suits directed against itself for reasons of violation of other patents whose priority date is prior to that of its own."



The disappearance of these "cover-up patents", as they are known, constitutes one of the most highly acclaimed achievements in the now not so recent reform of patents legislation in our country. The effect of this elimination is very clear and was explicitly included in the sentence issued by the First Courtroom of the Supreme Court on 19th October 1993 (RJ 7742):

"We must bear in mind that as the minutes contain a suit for reasons of infringement of patent rights filed in the name of Mr. José B.P., the nucleus of the question is, as the appealed sentence indicates, to determine if these machines manufactured by the defendant are equal to those patented by the plaintiff, which means that, as Art. 55 LP states, the holder of a patent may not invoke the latter to defend itself against suits directed against itself for reasons of violation of other patents whose priority date is prior to that of its own; whereas the priority, in this case, favours the appealed plaintiff, i.e. it is not a question of carrying out a comparative examination between the claims of each patent, but rather of determining if the machines that are said to have been built in infringement of the plaintiff's patent right are substantially identical to the machines protected by this patent, or on the contrary, if they introduce innovations that constitute inventive activity [...]"

(c) Even if we are to ignore these last two considerations, neither could the patent play any role in the controversy inasmuch as it would be a patent that would be "dependant" on ETHYPHARM, S.A.'s patent. In other words, its object could never be used for the manufacture of an Omeprazole whose formulation is protected by a previous patent. The dependence between patents is explicitly regulated in article 56 of the Act, according to which:

"The fact that the invention that is the object of a patent cannot be exploited without using the invention protected by a previous patent belonging to a different holder shall not be an obstacle to the validity of the patent. In this case, neither will the holder of the previous patent be allowed to exploit the ulterior patent during the term of validity of the latter without the consent of its holder and neither will the holder of the ulterior patent be allowed to exploit either of the two patents during the term of validity of the previous patent, unless it obtains the consent of the holder of same or has been given a mandatory license".

In other words, without detriment to the fact that the defendant may make use of the processes in its patent for other purposes, the use of same to produce Omeprazole according to the formulation patented by ETHYPHARM, S.A. would require the explicit consent of the latter, inasmuch as the object of this patent could not be exploited without using at the same time the invention protected in patent no. ES 9301319.

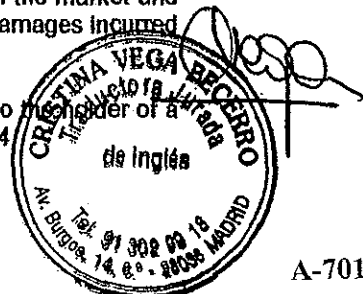
III

ACTIONS TO WHICH THE HOLDER OF THE PATENT RIGHTS IS ENTITLED

1. General regime

The Patents Act lays down in favour of the holder of an Industrial Property right a system of actions structured around three basic premises: the cessation of the infringing activity (suspension of the manufacture and sale of the infringing product), the removal of the property and instruments used in the infringement (removal from the market and destruction of illegal specimens) and the restitution for the losses and damages incurred (financial compensation).

Thus, article 62 of the act lays down that the holder of a patent and also the holder of a utility model by virtue of the references contained in articles 152 and 154



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I HEREBY BEG THE COURT to consider the above statement for the opportune purposes.

SECOND ADDITIONAL PLEADING. Requirement for defendant to show documentation.

That this party is interested, in accordance with the terms of article 328 of the Civil Prosecution Act, that when LABORATORIOS BELMAC, S.A. be summoned to answer the suit, the defendant be requested to provide the following documentation along with its answer:

- (a) A copy of the pages in the Manufacture Protocols for Batches Z 104, Z 112 and Z 093 of Omeprazole that state the pharmaceutical speciality or destination to which they are referred.
- (b) A copy of pages 33 of 33 of the Manufacture Protocol for Batches Z 022 Z 030, Z 033, Z 029 and Z 051 of Omeprazole that state the final balance of the batches.
- (c) A copy of the manufacture and sale contracts entered into by LABORATORIOS BELMAC, S.A. after 24th March 2002 regarding the pharmaceutical speciality Omeprazole.
- (d) A copy of the licenses or leases entered into with third parties by LABORATORIOS BELMAC, S.A. regarding the pharmaceutical authorisations obtained for the speciality Omeprazole.
- (e) A copy of the pages in the Manufacture Protocol for the batches of Belmazol 20 mg. Omeprazole capsules (S1); Davur 20 mg (V008); Belmazol 20 mg. (V003) and Omeprazole Famygel (V 034), that state the formulation and the final balance.
- (f) A complete list of the Omeprazole pharmaceutical specialities manufactured by LABORATORIOS BELMAC, S.A. for itself or for third parties and destined for exportation after 23rd March 2002.
- (g) The total volume, certified by auditor, of kilos of Omeprazole manufactured since 23rd March 2002 for the aforementioned pharmaceutical specialities.

I HEREBY BEG THE COURT that in accordance with the above pleading, request in the letter rogatory that the defendant provide the above documentation along with its answer to the suit.

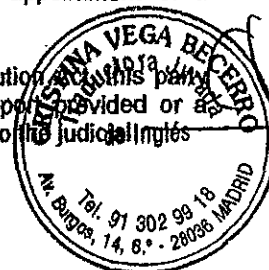
ADDITIONAL THIRD PLEADING: Judicial appointment of an expert accountant.

- In accordance with the terms of article 339.2 of the standing Civil Prosecution Act, this party is interested in the judicial appointment of an expert accountant in order that so that by analysing the invoices, official books, accounting documents and any other necessary document owned by the company ETHYPHARM, S.A. or by the defendant LABORATORIOS BELMAC, S.A., it may be possible to certify: (i) the average price that LABORATORIOS BELMAC, S.A. paid to ETHYPHARM, S.A. for the manufacture and sale of Omeprazole pharmaceutical specialities (ii) the price that LABORATORIOS BELMAC, S.A. should have paid to ETHYPHARM, S.A. for the manufacture and sale by LABORATORIOS BELMAC, S.A. of Omeprazole specialities after 23rd March 2002.

I HEREBY BEG THE COURT to consider the above pleading for the opportune purposes.

FOURTH ADDITIONAL PLEADING. Reservation made for the judicial appointment of a technical expert.

In accordance with the terms of article 339.2 of the standing Civil Prosecution Act, this party wishes, for the case of a challenge by the defendant of the expert's report provided or a discrepancy regarding its content and scope, that the Court should proceed to the judicial inquiries



appointment of an expert, whereas we hereby propose the Patents Centre in the University of Barcelona. Professor. Pascual Segura, the Director of this centre, enjoys great prestige and is highly specialised in the issue of decisions regarding pharmaceutical patents. Articulation of the evidence and specification of what should be examined shall be carried out depending on the answer to the suit, in the prior Hearing proceeding or at the Court's request. The address of this Centre is as follows:

Parc Científic de Barcelona
Baldri Reixac, 4
08028 Barcelona

I HEREBY BEG THE COURT to consider the above pleading for the opportune purposes.

FIFTH ADDITIONAL PLEADING, that at the time of filing this suit, my client did not yet have Spanish translations of documents 9, 35 and 36. This translation shall be presented as soon as this party receives it.

I HEREBY BEG THE COURT to consider the above pleading for the opportune purposes.

SIXTH ADDITIONAL PLEADING, that as the power of attorney attached is of a general nature for lawsuits,

I HEREBY BEG THE COURT to agree to register it and return it to this party, after entering it in the Minutes.

SEVENTH ADDITIONAL PLEADING, that in accordance with the terms of article 253 of Act 1/2000, this party hereby declares that the dimensions of the claim in this suit has not been determined and that the said claim does not affect the kind of suit applicable.

I HEREBY BEG THE COURT to consider the above pleading for the opportune purposes.

EIGHTH ADDITIONAL PLEADING, that this party has entrusted the legal direction of this proceeding to the Attorneys of the Illustrious Solicitors' Association of Madrid, Mr. Antonio Castán Pérez-Gómez (Member no. 24, 841) and Mr. Enrique Arnijo Chávarri (Member no. 28, 816), both of whom have their professional offices in Madrid, at calle de Miguel Ángel no. 21 (Telephone: 91 700 94 00).

I HEREBY BEG THE COURT to consider the above pleading for the opportune purposes.

NINTH ADDITIONAL PLEADING, that in application of Art. 135.1 of the Civil Prosecution Act 1/2000, the attached writ that is subject to a deadline is presented before three o' clock in the afternoon of the working day following expiry of the deadline.

I HEREBY BEG THE COURT to consider the above pleading for the opportune purposes.

In witness whereof, I hereby request Justice in Madrid on the date of April 11th, 2005.

Antonio Castán

Certificación
Don/Doña Cristina Vega Becerro
Intérprete Jurado de Idiomas
certifica que la que antecede es traducción fiel y completa al Idioma Español
de un documento redactado en Idioma Inglés
En Madrid a 13 Julio 2005
FIRMA Cristina Vega Becerro

